UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION ***This Documents Relates to All Actions***	**MDL No. 2875** **Honorable Robert B. Kugler, District Judge**

MEMORANDUM OF LAW IN SUPPORT OF ZHP DEFENDANTS' OBJECTIONS TO AND MOTION TO REVERSE SPECIAL MASTER ORDER NO. 84

INTRODUCTION

Pursuant to Rules 34 and 53 of the Federal Rules of Civil Procedure, Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, the "ZHP Defendants") object to the Special Master's ruling in Special Master Order No. 84 ("SMO 84") and ask the Court to reverse that ruling and to require third-party Valisure LLC ("Valisure") to respond to the ZHP Defendants' narrow Rule 45 subpoena seeking the production of plainly relevant information.

BACKGROUND

On December 14, 2022, the ZHP Defendants issued a subpoena to Valisure seeking the production of ***one*** piece of information: the National Drug Code ("NDC") number associated with certain valsartan-containing drugs ("VCDs") manufactured by Novartis that Valisure tested in connection with a Citizen Petition related to the presence of alleged impurities. (ECF No. 2217-4.) Notably, the Citizen Petition identified the presence of detectable levels of NDMA in the Novartis product that Valisure tested. (ECF No. 1984-1, Valisure Cit. Pet., at Appendix A.) This is significant because Novartis manufactures brand-name Diovan, which Plaintiffs and their experts in this litigation claim did not contain ***any*** NDMA.[1] (*See,*

[1] According to Plaintiffs, the presence of NDMA at ***any*** level above zero in at-issue VCDs during the class period rendered those products adulterated insofar as

e.g., ECF No. 2033-3 at ¶ 33.) Plaintiffs, however, have suggested that the Novartis product that Valisure tested may be: (i) generic product; or (ii) product manufactured by Novartis for a non-U.S. market. (ECF No. 2023 at 4-5.) Although neither of these theories is plausible,[2] the ZHP Defendants sought confirmation from Valisure that the Novartis product it tested was, in fact, Diovan sold in the U.S. market, in order to fairly defend itself against plaintiffs' claims.

In response to the ZHP Defendants' subpoena, Plaintiffs and Valisure objected, arguing that the ZHP Defendants sought information that was irrelevant, constituted an undue burden, and was untimely. (ECF Nos. 2217-5 and 2217-6.) The ZHP Defendants filed a Motion to Compel Compliance with the Subpoena (ECF No. 2217), and Plaintiffs moved for a protective order (ECF No. 2228). Briefing on the competing motions closed on January 23, 2023, with oral argument occurring shortly thereafter.

On August 29, 2023, the Special Master issued SMO 84, denying the ZHP Defendants' Motion to Compel and quashing the subpoena on the basis that it was untimely served. (ECF No. 2476.) The Special Master found that the information

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they contained nitrosamine impurities that were not present in Diovan, the Reference Listed Drug for generic valsartan.

[2] Defendants' Motion to Compel the Production of Testing and Other Materials in the Possession of Class Expert, Ron Najafi (ECF No. 2013), which the Court granted, debunked Plaintiffs' suggestion that the Novartis product tested by Valisure was anything other than brand-name Diovan.

the ZHP Defendants seek from Valisure is relevant, noting that "discovery had been ordered with respect to the purported validation of the Valisure testing by one of Plaintiffs' experts, Dr. Najafi." (*Id.* at 3.) The Special Master did not address burden for obvious reasons; the subpoena simply asks for the disclosure of an 11-digit NDC number, something that can be accomplished in a few minutes, and is neither broad nor remotely burdensome. Even so, the Special Master denied the ZHP Defendants' motion, holding that the subpoena was untimely. According to the Special Master, "The ZHP Defendants have not offered any compelling justification for waiting until December of 2022, more than one year after the close of fact discovery, to seek information from Valisure concerning its testing." (*Id.*) The ZHP Defendants seek review of this finding, which is inconsistent with the operative case management orders and procedural posture of this MDL proceeding.

STANDARD OF REVIEW

This Court's review of decisions issued by the Special Master is governed by Rule 53. *See, e.g.*, *Nippon Steel & Sumitomo Metal Corp. v. POSCO*, No. 12-2429, 2014 U.S. Dist. LEXIS 42444, at *1 (D.N.J. Mar. 26, 2014). Objections to the Special Master's decision are subject to *de novo* review, unless the parties stipulate otherwise. Fed. R. Civ. P. 53(f)(3). "Upon review, the [c]ourt may 'adopt or affirm, modify, wholly or partly reject or reverse, or resubmit to the master with

instructions.'" *Ramos v. Banner Health*, No. 15-cv-2556, 2018 U.S. Dist. LEXIS 138101, at *6 (D. Colo. Aug. 8, 2018) (citation omitted).

ARGUMENT

The Court should sustain the ZHP Defendants' objections to SMO 84 and compel Valisure's compliance with the narrow subpoena for two reasons: (1) the subpoena was timely; and (2) even if it were not, there is good cause for enforcing the subpoena because the discovery would not cause any prejudice to Valisure or Plaintiffs.

First, the Special Master erred in finding that the ZHP Defendants' subpoena was not timely because it was issued "more than eighteen months after the June 1, 2021 deadline for the completion of the '***first*** phase of fact discovery.'" (ECF No. 2476 at 1 (emphasis added) (citation omitted).) The reference to the "first" phase of discovery expressly confirms that further discovery is contemplated in this MDL proceeding. Although the Special Master invoked CMO 23, that order was limited to initial Rule 34 discovery, primarily related to Plaintiffs' efforts to conduct depositions of the VCD Manufacturer Defendants' witnesses, and initial corporate depositions of the Wholesaler and Retailer Defendants. To the extent CMO 23 imposed any deadlines relating to third-party discovery, they were limited to fact depositions of treating and prescribing physicians of bellwether personal injury Plaintiffs. In short, those deadlines have nothing to do with the limited Rule 45

discovery at issue here: third-party subpoenas for testing information from entities like Valisure.

Moreover, the course of this sprawling, multi-year proceeding confirms that CMO 23 was never intended to preclude additional fact discovery. While CMO 23 references two specific "phases" of discovery, both Plaintiffs and Defendants have been permitted to conduct additional fact discovery subsequent to the deadlines established in CMO 23. For instance, Defendants have sought and have been permitted to conduct further discovery related to Plaintiffs' TPP class claims. Less than two months prior to the issuance of the at-issue subpoena, Defendants moved for additional discovery from Plaintiffs' TPP class representative. (ECF No. 2178.) The Special Master granted that motion despite Plaintiffs' contention that the requests were untimely, noting that timeliness did not even "factor into the decision whether to compel production of the documents in question." (*See* SMO 73 at 3, ECF No. 2249.) Likewise, Plaintiffs are in the process of conducting custodial ESI and deposition discovery of the Wholesaler and Retailer Defendants related to valsartan, as well as extensive document and deposition discovery of all Defendants named in the losartan and irbesartan actions. The suggestion that CMO 23 effectively ended fact discovery in this MDL proceeding is nonsensical.

SMO 84 also suggests that the discovery was improper because the subpoena was issued after "Plaintiffs presented their expert witness reports on liability and

well after briefing and decisions on class certification issues." (ECF No. 2476 at 4.) However, that is not true. The subpoena was issued while Rule 23 motions were still pending, and although expert witness reports concerning liability issues had been disclosed by Plaintiffs a little more than a month prior to the subpoena, those opinions were focused on manufacturer-specific quality and regulatory issues. Accordingly, the Special Master's finding that the subpoena was untimely is erroneous and should be vacated.

Second, even if the Court agrees with the Special Master's finding that the ZHP Defendants' subpoena was untimely issued, it should nonetheless compel compliance with the subpoena because the ZHP Defendants acted in good faith, and enforcement of the subpoena would not cause any prejudice. The subpoena was the culmination of prior efforts by the ZHP Defendants to obtain information from Dr. Najafi regarding the validation testing that he performed, per his deposition testimony, in connection with Valisure's Citizen Petition—discovery ordered by the Special Master. (ECF No. 2013.) Although Dr. Najafi produced responsive documents on August 22, 2022 (*see* email from D. Nigh to Defendants' Executive Committee (Ex. 1 to Certification of Jessica Davidson)), Defendants ultimately determined that Dr. Najafi's validation testing was "blind." Because Defendants could not confirm what specific valsartan product Dr. Najafi had tested or the NDC numbers of products Valisure had tested, they were required to issue the Rule 45

subpoena to obtain that information. Failing to enforce the subpoena would effectively nullify the Special Master's prior ruling that Defendants are entitled to this information and deny them the opportunity to challenge Plaintiffs' claims regarding VCDs manufactured by Novartis.

By contrast, compelling the requested discovery would not cause any prejudice to Valisure or Plaintiffs. The subpoena is so narrow and non-burdensome that Valisure could comply in just a few minutes, far less time than it took Valisure and Plaintiffs to object to the request. Nor would enforcement of the subpoena materially delay the proceedings. There remains no date set for an initial trial in this MDL, no deadline for Rule 56 motions, no deadline for *Daubert* motions regarding damages experts, no entry (or submission) of an operative class notice proposal, no deadlines for pretrial motions, and no date for a pretrial conference. And Defendants have not even been permitted to raise jurisdictional defenses at this juncture, further underscoring the relatively early stage of these proceedings. Simply put, even assuming the subpoena ran afoul of some deadline (and it did not), basic fairness justifies extending the time for Defendants to obtain information that the Special Master made clear is relevant to the claims or defenses in this litigation.

CONCLUSION

For the reasons discussed above, the ZHP Defendants respectfully object to the Special Master's ruling in SMO 84, and asks the Court to reverse SMO 84 to require Valisure to comply with the ZHP Defendants' subpoena.

Dated: September 19, 2023

Respectfully submitted,

By: /s/ *Jessica Davidson*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 19, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
Jessica Davidson